IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

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| RIVER'S EDGE PHARMACEUTICALS, LLC, | ) | |
| Plaintiff, | ) | |
| v. | ) | 1:10CV991 |
| GORBEC PHARMACEUTICAL SERVICES, INC., and J. MICHAEL GORMAN, | ) | |
| Defendants. | ) | |

ORDER AND MEMORANDUM OPINION

BEATY, Chief Judge.

This matter is presently before the Court on a Motion for Preliminary Injunction [Doc. #11] filed by Plaintiff River's Edge Pharmaceuticals, LLC ("Plaintiff") seeking injunctive relief with respect to Defendant Gorbec Pharmaceutical Services, Inc. ("Defendant Gorbec"). Plaintiff originally filed a Motion for Temporary Restraining Order, Expedited Discovery, and Preliminary Injunction [Doc. #11] on January 25, 2010. After a three week period, during which the parties represented to the Court that negotiations were taking place, Plaintiff filed an Emergency Motion for Expedited Scheduling [Doc. #31] wherein Plaintiff sought renewal of its Motion for Temporary Restraining Order following the breakdown of those negotiations. In an Order dated February 24, 2011 [Doc. #38], this Court denied Plaintiff's Motions for Temporary Restraining Order and for Expedited Scheduling. However, the Court extended to Plaintiff and Defendant Gorbec the opportunity to conduct limited discovery prior to a preliminary injunction, and scheduled a hearing on Plaintiff's Motion for Preliminary Injunction.

A hearing on Plaintiff's Motion for Preliminary Injunction was held before this Court on March 2, 2011.

## I. BACKGROUND

This case involves a business relationship between Plaintiff and Defendant Gorbec relating to the development and testing of certain generic drugs and medical devices for purposes of obtaining FDA approval to market such products. According to Defendant Gorbec, its business "helps other pharmaceutical companies develop, manufacture, analyze, and gain FDA approval for pharmaceutical products." (Def.'s Opp'n Brief, Doc. #28, at 2). In 2007, Plaintiff engaged Defendant Gorbec to develop certain of Plaintiff's generic drugs and guide Plaintiff through the Abbreviated New Drug Application ("ANDA") process for FDA approval of those drugs. Plaintiff also engaged Defendant Gorbec to aid in obtaining FDA approval for certain medical devices under what is known as a 510(k) submission, which is a process similar in nature to the ANDA process for generic drugs. The approval process for these generic drugs and medical devices spans several years during which time the FDA oversees a highly regulated process of development, testing, and data reporting before an application can be approved and a product can be placed on the market. Plaintiff contends that the timing of this process is critical to applicants because typically only the first company to obtain approval from the FDA can successfully market its product. In addition, Plaintiff contends that the approval process is confidential such that pharmaceutical companies engaged in the application process know where they stand in relation to any others who might be vying for the same place in the market. As a part of the work associated with the ANDA and 510(k) processes,

Defendant Gorbec conducted the FDA required stability testing on Plaintiff's products, communicated with the FDA as necessary, and filed the ANDA and 510(k) submissions with the FDA on behalf of Plaintiff. In addition to its involvement in the ANDA and 510(k) processes, Defendant Gorbec worked with Plaintiff for a period of time to develop certain Drug Efficacy Study Implementation products ("DESI drugs").

Plaintiff contends that the once amicable relationship between Plaintiff and Defendant Gorbec changed in August 2010 when Defendant Gorbec proposed a manufacturing agreement between the parties that would grant Defendant Gorbec ownership rights in certain work product, including "formulas, technological knowhow, manufacturing methods, and procedures." (Pl.'s Sealed Brief, Doc. #14, at 9). Plaintiff further contends that in the following months, Defendant Gorbec took a number of actions which led Plaintiff to file for injunctive relief. Plaintiff contends that Defendant Gorbec asserted ownership over the formulations and manufacturing processes (collectively "the Processes") related to the ANDA and 510(k) products, which Plaintiff contends it hired Defendant Gorbec to develop, and over which Plaintiff claims ownership. Plaintiff further contends that Defendant Gorbec refused to disclose information related to the ANDA and 510(k) products, including the Processes, which Plaintiff claims is necessary to effectuate a technology transfer of the ANDA and 510(k) products to another manufacturer and continue the FDA approval process. Plaintiff also contends that Defendant Gorbec threatened to directly compete with Plaintiff by using the Processes to obtain approval on the very generic drugs and medical devices at issue in this case. Plaintiff further contends that Defendant Gorbec intends to do this for the benefit of another pharmaceutical

company and to the detriment of Plaintiff.

Plaintiff contends that Defendant Gorbec's alleged conduct led Plaintiff to file for injunctive relief in which it seeks to: (1) require Defendant Gorbec to provide Plaintiff all information relevant to the ANDA and 510(k) products, including the applications themselves, all drug formulations and master drug files, all communications with the FDA, and all information related to the Processes at issue; (2) require Defendant Gorbec to cooperate in a technology transfer, including continuation of the FDA required stability testing; (3) require Defendant Gorbec to be prohibited from transferring, destroying, disclosing, or using (other than for the benefit of Plaintiff) any of the information associated with Plaintiff's ANDA and 510(k) products; and (4) require Defendant Gorbec to be prohibited from competing against Plaintiff with respect to the ANDA and 510(k) projects on which Defendant Gorbec has been engaged by Plaintiff. In support of its request for such relief, Plaintiff contends that, based on Defendant Gorbec's conduct, and based on the time-sensitive nature of the ANDA and 510(k) processes, if injunctive relief does not issue, Plaintiff will suffer irreparable harm to its ability to obtain timely FDA approval for its generic drugs and medical devices and it will lose its opportunity to be the first to market those products.

The Court notes however that at the March 2, 2011 hearing, Plaintiff acknowledged that during the period of negotiations and limited discovery leading up to the hearing, Defendant Gorbec has turned over much of the information sought by Plaintiff in its request for injunctive relief. Defendant Gorbec, in response, stated that it indeed has turned over all of the requested information to Plaintiff, including that information revealing the Processes at issue. Plaintiff

stated that it is in the process of reviewing all of the information submitted by Defendant Gorbec and that it may have follow-up inquiries which would require Defendant Gorbec's assistance during the transfer of technology to another manufacturer. As to the issue of continued stability testing, Plaintiff indicated that it would pay Defendant Gorbec a reasonable price for any such services rendered during the period of time required to effectuate the technology transfer subject to a final accounting of the amount of the real costs to Defendant Gorbec. Furthermore, as to issues related to the Processes, Defendant Gorbec stated that it does not intend to use the Processes to directly compete with Plaintiff, but rather Defendant Gorbec only intends to use such information as it would be applicable to other projects with other clients not related to Plaintiff or its products. Based on Defendant Gorbec's briefing of this matter and its statements made at the hearing, Defendant Gorbec has asserted ownership only as to the Processes, and not to the ANDA or 510(k) products or other associated information. Taking all of this information into account, Plaintiff stated at the hearing that it still requests injunctive relief similar to that set forth in Motion for Preliminary Injunction to the extent that such relief would require Defendant Gorbec to "do what they say they are willing to do," including disclosing all relevant information presently and throughout the technology transfer if necessary, continuing stability testing for compensation, and refraining from direct competition with Plaintiff's ANDA and 510(k) products. The Court nevertheless will undertake a review of the basis of and legal support for Plaintiff's request for the issuance of a preliminary injunction.

## II. PRELIMINARY INJUNCTION

A preliminary injunction is an extraordinary and drastic remedy. A movant must establish four elements before a preliminary injunction may issue: (1) he is likely to succeed on the merits; (2) he is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in his favor; and (4) an injunction is in the public interest. Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7, --, 129 S. Ct. 365, 374, 172 L. Ed. 2d 249 (2008). All four elements must be satisfied. Id. The purpose of a preliminary injunction is to "protect the status quo and prevent irreparable harm during the pendency of a lawsuit" in a manner that would "preserve the court's ability to render a meaningful judgment on the merits of the case." In re Microsoft Corp. Antitrust Litig., 333 F.3d 517, 525 (4th Cir. 2003). Relief sought under a preliminary injunction may be prohibitory or mandatory in nature. See Wetzel v. Edwards, 635 F.2d 283, 286 (4th Cir. 1980). However, if the movant seeks mandatory injunctive relief, such relief often does not serve to protect the status quo and, in such cases, the movant will be held to a heightened burden of showing that "the exigencies of the situation demand such relief." Id. Defendant Gorbec contends that certain relief sought by Plaintiff in this case is mandatory in nature and requires a heightened showing by Plaintiff as to the preliminary injunction factors. Plaintiff does not dispute the fact that some of its requests are for mandatory relief. Therefore, to the extent that Plaintiff seeks mandatory injunctive relief in this case, the Court will address, where applicable, whether the issuance of such relief would require a heightened showing by Plaintiff, and whether Plaintiff has met its burden.

In considering the parties' briefing on Plaintiff's Motion for Preliminary Injunction, as

well as the arguments made at the hearing on March 2, 2011, the Court acknowledges that the primary issue for the Court's attention at this time involves whether Plaintiff has met its burden under the preliminary injunction standard as to the question of who rightfully can claim ownership of the Processes used in the development of the ANDA drugs and 510(k) medical devices.[1]

Plaintiff first contends that it is likely to succeed on the merits of its claim to ownership of the Processes at issue in this case because Plaintiff provided Defendant Gorbec with the initial product ideas and hired and paid Defendant Gorbec "to formulate and develop products." (Pl.'s Reply Brief, Doc. #41, at 5). Plaintiff further contends that the contractual agreements between Plaintiff and Defendant Gorbec do not provide Defendant Gorbec with ownership rights in the Processes. As such, Plaintiff contends that, absent a contract expressing the ownership rights of each party, "[t]he fruit of the labor of one who is hired to invent, accomplish a prescribed result, or aid in the development of products belongs to the employer." Speck v. N.C. Dairy Found., Inc., 311 N.C. 679, 686, 319 S.E.2d 139, 143 (1984); see also Houghton v. United States, 23 F.2d 386, 390 (4th Cir. 1928) ("It matters not in what capacity the employee may originally have been hired, if he be set to experimenting with the view of making an invention, and accepts pay for such work, it is his duty to disclose to his employer what he discovers in making the experiments, and what he accomplishes by the experiments belongs to

[1] The Court notes that Plaintiff has raised a claim of breach of fiduciary duty, among other claims, against Defendant Gorbec. However, for purposes of this preliminary injunction, the Court will limit its consideration to whether injunctive relief should issue based on Plaintiff's showing regarding ownership of the Processes. As such, the Court makes no findings under this Order as to any of Plaintiff's other claims at this time.

the employer."). Therefore, Plaintiff contends that it owns the Processes used in the formulation and development of the ANDA and 510(k) products, and Defendant Gorbec cannot now claim such ownership for itself. In opposition to Plaintiff's claimed ownership of the Processes, Defendant Gorbec contends that the contracting documents and the dealings of the parties over the course of the business relationship favor Defendant Gorbec's assertion of ownership as to the Processes at issue. In support of its position, Defendant Gorbec contends that it has always claimed ownership over the Processes and that it made such claim known to the Plaintiff by redacting information related to the Processes in communications with Plaintiff over the course of the ANDA and 510(k) submission process. Defendant Gorbec further contends that Plaintiff never objected to the redaction of that information and cannot now assert ownership over that information.[2]

Considering all the evidence, the Court concludes, without deciding the question of the ownership in the Processes, that Plaintiff has shown a likelihood of success on the merits of its claim of ownership over the Processes. The Court finds that Plaintiff's evidence suggests that the nature of the business relationship between Plaintiff and Defendant Gorbec was one in which Defendant Gorbec was hired for the specific purpose of formulating and developing

[2] Based on the briefing submitted by the parties and the statements made at the March 2, 2011 hearing, it is not clear to the Court whether Defendant Gorbec "redacted" information about the Processes from communications with Plaintiff by leaving such information out of those communications altogether or by affirmatively representing to Plaintiff that such information was hidden from Plaintiff's view of the communications. To the extent that Defendant Gorbec "redacted" information about the Processes by leaving such information out of the communications sent to Plaintiff altogether, it is not clear how Plaintiff could have known, based on that method of "redaction", that Defendant Gorbec asserted any claim of ownership over the Processes, as Defendant Gorbec contends Plaintiff so knew.

generic drugs and medical devices for Plaintiff. In addition the Court finds that the evidence currently before the Court does not provide a clear indication that any contract provision agreed to by Plaintiff and Defendant Gorbec establishes the terms of ownership of the Processes of any party in this action. Therefore, in the absence of a contract provision to the contrary, the Court finds that Plaintiff, as the hiring party, has made a sufficient showing that it is likely to succeed on the merits of its ownership claim as to the Processes.[3]

Plaintiff next contends that it will suffer irreparable harm (1) if Defendant Gorbec is not required to cooperate in providing to Plaintiff all information regarding the ANDA and 510(k) products, including the Processes, so that Plaintiff may undertake a technology transfer to another manufacturing company, and (2) if Defendant Gorbec is not prohibited from transferring, disclosing, or using that information in any manner that would directly compete with Plaintiff's ANDA and 510(k) products. Plaintiff asserts this claim of irreparable harm on the notion that the applications for the generic drugs and medical devices at issue involve a race among pharmaceutical companies to obtain first approval of the products, as typically only the first company to get such approval can successfully market their products. As such, Plaintiff contends that any delay in the application process due to Defendant Gorbec's inaction, intentionally or otherwise, will cause irreparable harm by preventing Plaintiff from obtaining the

[3] The Court notes that because the question of ownership as to the Processes is not resolved by this Order, any use of the Processes, even within the bounds of this Order, is taken with the awareness that such use may be against the opposing party's ownership interest and may be subject to an accounting of damages for such use at a later time in the litigation. To protect the ownership interest of the true owner, any permitted use of the Processes under this Order will require that the parties take extreme care with respect to maintaining confidentiality as to the Processes during the pendency of this litigation.

first approval by the FDA for its products. With respect to the Processes specifically, Plaintiff contends that the specific information associated with the Processes is critical to the approval process of the ANDA and 510(k) products at issue in this case. According to Plaintiff, the FDA requires consistency in "the precise formula, mixing sequence and conditions, batch formulation and other aspects of the manufacturing process," (Pl.'s Reply Brief, Doc. #41, at 2), and any changes to that information require additional approval from the FDA and potentially years of additional testing. As such, Plaintiff contends that if Defendant Gorbec does not provide Plaintiff with the requested information or, to the extent that Defendant Gorbec has already provided certain information, does not continue cooperating with Plaintiff if additional or different information is needed, Plaintiff will be unable to make an effective technology transfer and continue with the ANDA and 510(k) processes for the products Defendant Gorbec had already begun developing on behalf of Plaintiff. Plaintiff contends that without the Processes, any new manufacturer engaged by Plaintiff would have to start over to develop the missing formulations and manufacturing processes. As such, the required approval of those changes by the FDA would cause inevitable delay in the ANDA and 510(k) processes, and that delay would irreparably harm Plaintiff's attempt at obtaining first approval for its products. Plaintiff also contends that it will suffer similar irreparable harm if Defendant Gorbec is not required to continue conducting the FDA required stability testing on Plaintiff's products. Plaintiff contends that any delay or cessation of the stability testing would set back the application processes such that Plaintiff would essentially be unable to timely obtain approval for its products.

In addition to asking the Court to mandate certain actions with respect to Defendant Gorbec, Plaintiff seeks to prohibit Defendant Gorbec from transferring, disclosing, or using information related to the ANDA and 510(k) products, including the Processes, in any manner that would compete directly with Plaintiff's ANDA and 510(k) products. Plaintiff contends that it will suffer irreparable harm if Defendant Gorbec is not prohibited from acting for its own benefit or for the benefit of some other company in pursuing the same ANDA and 510(k) products over which Plaintiff is attempting to obtain approval. Plaintiff further contends that such direct competition with the cooperation of Defendant Gorbec would destroy Plaintiff's chance of obtaining first approval by the FDA.

In opposition, Defendant Gorbec contends that it has already turned over all relevant information to Plaintiff including information regarding the Processes at issue. In addition, Gorbec contends that it has continued and will continue the required stability testing during the technology transfer process, provided Plaintiff compensate Defendant Gorbec for the costs of such services. At the March 2, 2011 hearing, Plaintiff stated that it would not expect Defendant Gorbec to undertake any continued action without reasonable payment for services rendered.

As an additional matter, although Defendant Gorbec contends that although there is no non-competition agreement between the parties, Defendant Gorbec asserts that it has no intention of directly competing with Plaintiff as to the products at issue in this case. Rather, Defendant Gorbec contends that any use made of the Processes, which Defendant Gorbec claims it owns, will be for purposes other than direct competition with Plaintiff. Specifically, Defendant Gorbec contends that it will not be prohibited from assisting in the manufacture of

other products for other clients. To this last point, Plaintiff has stated that it would not object to Defendant Gorbec's use of the Processes for purposes other than direct competition with Plaintiff's generic drugs and medical devices.

Considering all the evidence, the Court nevertheless finds that Plaintiff has shown that irreparable harm would result absent injunctive relief in this case. Specifically, the Court finds that Plaintiff's evidence suggests that the Processes are a key component to the ANDA and 510(k) process. In addition, the Court finds that, given the time-sensitive nature of the application process, without the Processes, Plaintiff will likely be unable to undertake a full and effective technology transfer of its products to another manufacturer. Therefore, it is likely that irreparable harm to Plaintiff's ability to timely continue with the ANDA and 510(k) submissions would result unless Defendant Gorbec has in fact already turned over to Plaintiff the information it needs. In addition, the Court finds that cessation or delay in the stability testing process, a necessary component in continuing the ANDA and 510(k) process, would also likely result in irreparable harm to Plaintiff's efforts to obtain approval for its products. Plaintiff agrees, however, that payment to Defendant Gorbec for such services would be required. Finally, the Court finds that irreparable harm would likely result to Plaintiff if Defendant Gorbec engaged in a transfer, disclosure, or use of the Processes in a manner that would directly compete with Plaintiff's products. As such, the Court finds that Plaintiff would be entitled to injunctive relief. Such injunctive relief, however, would not extend to Defendant Gorbec's use of the Processes for purposes other than direct competition with Plaintiff.

Plaintiff next contends that the balance of equities tip in Plaintiff's favor with respect to

granting Plaintiff's requested injunctive relief. Plaintiff contends that Defendant Gorbec acted improperly and illegally when it originally refused to turn over documents relevant to Plaintiff's ANDA and 510(k) products, asserted ownership over the Processes and refused to disclose them to Plaintiff, and threatened to directly compete with Plaintiff on its products. Plaintiff contends that it has taken a large financial risk during the ANDA and 510(k) process and has paid Defendant Gorbec approximately $10 million dollars throughout the ANDA and 510(k) process. As such, Plaintiff contends that it would be inequitable for Defendant Gorbec now to take the benefit of Plaintiff's risk by withholding or using the Processes or other information for Defendant Gorbec's benefit and to the detriment of Plaintiff. In opposition, Defendant Gorbec contends, as stated above, that it has already turned over all relevant information to Plaintiff and that it does not intend to use the Processes to directly compete with Plaintiff on its products. Defendant Gorbec also contends that Plaintiff is delinquent on payments to Defendant Gorbec for stability testing and associated costs, and should not now be rewarded with the injunctive relief sought. Defendant Gorbec further contends that Plaintiff created the situation in which the parties now find themselves by failing to notify Defendant Gorbec of a warning letter from the FDA regarding production of DESI drugs. Defendant Gorbec contends that the warning letter ordered Plaintiff to stop production of the DESI drugs, as were being produced by Defendant Gorbec, but Plaintiff instead continued production of DESI drugs with another manufacturer against the FDA's orders. In addition, Defendant Gorbec contends that Plaintiff's actions with respect to the DESI drugs have ruined any chance that the FDA would grant approval of any of Plaintiff's ANDA or 510(k) products. Based on statements made at the

March 2, 2011 hearing, Plaintiff disagrees with Defendant Gorbec's position and contends that it has complied with the warning letter from FDA regarding the DESI drugs. Plaintiff further contends that the warning letter has no impact on Plaintiff's ANDA and 510(k) products going forward.

Considering all the evidence the Court finds that the balance of equities support granting Plaintiff injunctive relief in this case, but not insofar as such relief would prohibit Defendant Gorbec from continuing its business with other clients. Specifically, to the extent that Plaintiff seeks relief that would prohibit Defendant Gorbec from using the Processes to compete directly with Plaintiff on the ANDA and 510(k) products, such injunctive relief could not, in the balance of equities, extend to Defendant Gorbec's use of the Processes for other applications which would not directly compete with Plaintiff's ANDA and 510(k) products. It was not asserted that Plaintiff contends otherwise. Therefore, the Court's granting of an injunction for Plaintiff would not extend as far as to prohibit such use by Defendant Gorbec.

Plaintiff finally contends that the public interest favors injunctive relief in this case in that permitting Plaintiff to timely continue the ANDA and 510(k) submission process affords the public with generic products "critical to controlling the cost of healthcare." (Pl.'s Sealed Brief, Doc. #14, at 19). Plaintiff contends that injunctive relief could therefore only help the public and would not cause the public any harm. In opposition, Defendant Gorbec contends that the public interest would be harmed by rewarding Plaintiff's actions whereby Defendant Gorbec alleges that Plaintiff has disregarded FDA instructions with respect to continued production of DESI drugs. At the March 2, 2011 hearing, Plaintiff stated in response to Defendant Gorbec's

contentions, that Plaintiff was no longer involved in production of DESI drugs and that past production for the period prior to the FDA warning letter was not contrary to FDA regulations. Plaintiff contends that it has complied with and continues to comply with FDA regulations regarding DESI drugs. Considering all the evidence the Court finds that public interest would be served by granting injunctive relief which would allow Plaintiff's ANDA and 510(k) products to move forward in the FDA approval process.

To the extent that the Court's findings under any prong of the preliminary injunction analysis would require Defendant Gorbec to affirmatively act under this Order, either by continuing stability testing or by disclosing information to Plaintiff, Defendant Gorbec would argue that such relief is mandatory in nature and would thus require a heightened showing by Plaintiff of the preliminary injunction factors. With respect to the continuation of stability testing, the Court notes that such action would operate to maintain the status quo since Defendant Gorbec was undertaking the stability testing prior to this litigation and acknowledges that it intends to continue to do so through the technology transfer period. However, to the extent that continuation of stability testing or any other relief under this Order could be construed as mandatory relief, the Court finds that Plaintiff has shown that the exigencies of the circumstances in this case require such mandatory relief. See Wetzel, 635 F.2d at 286.

## III. CONCLUSION

Based upon the foregoing, the Court will partially GRANT Plaintiff's Motion for Preliminary Injunction as set forth herein. As to Plaintiff's request that Defendant Gorbec provide information regarding the ANDA and 510(k) products, including the Processes, the

Court notes that representations made at the March 2, 2011 hearing suggest that Defendant Gorbec has already provided Plaintiff with at least some of the requested information sought as part of Plaintiff's request for injunctive relief in this case. Plaintiff, however, contends it has not yet had time to verify the receipt of all such information. Based on the Court's findings set forth above, in order to facilitate the continuation of the ANDA and 510(k) application process that was proceeding prior to this litigation, the Court orders that Defendant Gorbec shall turn over the information requested by Plaintiff regarding the ANDA and 510(k) products, including the Processes at issue, within ten (10) days of the effective date of this Order. In addition, to the extent that Plaintiff requires additional or different information related to ANDA and 510(k) products in order to effectuate a technology transfer, Defendant Gorbec shall, without unnecessary delay, provide Plaintiff with the requested information. To the extent that Defendant Gorbec has provided Plaintiff with any information, the Court finds that Defendant Gorbec need not resubmit any such information pursuant to this Order.

As to Plaintiff's request regarding the continuation of stability testing in order to facilitate the continuation of the ANDA and 510(k) process that was proceeding prior to this litigation, Defendant Gorbec shall continue the stability testing for Plaintiff's ANDA and 510(k) products, as required by FDA regulations, until such time as Plaintiff can make a full and effective technology transfer to another manufacturer. However, to the extent that such stability testing shall continue, Plaintiff shall provide payment to Defendant Gorbec for any services rendered and associated costs, including Defendant Gorbec's designated hourly rate of $195. Plaintiff shall timely make such payments to Defendant Gorbec upon receipt of a Purchase Order from

Defendant Gorbec outlining, with specificity, the services rendered by Defendant Gorbec and the costs associated with those services. All money paid to Defendant Gorbec under this Order for the stability testing and technology transfer costs and services shall be subject to a final accounting review of the real costs to Defendant Gorbec as part of the ultimate resolution of all claims associated with the litigation between the parties in this case.

In addition, as to Plaintiff's request that Defendant Gorbec be prohibited from direct competition with Plaintiff on Plaintiff's ANDA and 510(k) products, the Court orders that Defendant Gorbec shall be prohibited from transferring, using, or disclosing any information related to Plaintiff's ANDA or 510(k) products, including the Processes at issue, except as set out herein. Defendant Gorbec also shall be prohibited from producing for itself or for any other person or entity, any of Plaintiff's ANDA or 510(k) products during the pendency of this litigation. However, Defendant Gorbec, without any apparent objection from Plaintiff, shall be permitted to use the Processes for the development or production of products, other than Plaintiff's ANDA or 510(k) products, for itself or for any other person or entity. The Court specifically notes that neither this provision nor any other provision of this Order resolves the ultimate question of ownership as to the manufacturing processes involved in this case.

Furthermore, because no provision of this Order resolves the question of ownership of the Processes at issue in this case, in order to protect the value of that interest, and to maintain the status quo in this case, Plaintiff and Defendant Gorbec shall take steps to ensure confidentiality during the pendency of this litigation on the part of the manufacturer to which the technology transfer is made, any associated agents or affiliates of that manufacturer, and any

persons or entities engaged by Defendant Gorbec as part of its work with other clients. Should it come to the attention of either Plaintiff or Defendant Gorbec that confidentiality has been or imminently will be undermined in some way, the Court, upon notice from the parties, will afford either party the opportunity to seek redress to address that concern at that time.

In addition, the Court notes that at the March 2, 2011 hearing, Plaintiff requested expedited scheduling to resolve the matter of the declaratory judgment action in this case. Finding that the relief provided under this Order adequately affords Plaintiff the opportunity to move forward with the FDA approval process for its ANDA and 510(k) products, the Court will deny Plaintiff's request for expedited scheduling as to the declaratory judgment action in this litigation.

Finally, the Court notes that it shall retain jurisdiction during the pendency of this litigation to interpret, enforce, or modify this Preliminary Injunction if appropriate.

IT IS THEREFORE ORDERED that Plaintiff's Motion for Preliminary Injunction [Doc. #11] is GRANTED as follows:

1. In order to facilitate the continuation of the ANDA and 510(k) application process that was proceeding prior to this litigation, Defendant Gorbec Pharmaceutical Services, Inc. shall hereby turn over the information requested by Plaintiff River's Edge Pharmaceuticals, LLC regarding the ANDA and 510(k) products, including the Processes at issue, within ten (10) days of the effective date of this Order. In addition, to the extent that Plaintiff requires additional or different information related to ANDA and 510(k) products in order to effectuate

a technology transfer, Defendant Gorbec shall hereby, without unnecessary delay, provide Plaintiff with the requested information. To the extent that Defendant Gorbec has provided Plaintiff with any information, the Court finds that Defendant Gorbec need not resubmit any such information pursuant to this Order.

2. In order to facilitate the continuation of the ANDA and 510(k) process that was proceeding prior to this litigation, Defendant Gorbec Pharmaceutical Services, Inc. shall hereby continue the stability testing for Plaintiff River's Edge Pharmaceuticals, LLC's ANDA and 510(k) products, as required by FDA regulations, until such time as Plaintiff can make a full and effective technology transfer to another manufacturer. However, to the extent that such stability testing shall continue, Plaintiff shall hereby provide payment to Defendant Gorbec for any services rendered and associated costs, including Defendant Gorbec's designated hourly rate of $195. Plaintiff shall timely make such payments to Defendant Gorbec upon receipt of a Purchase Order from Defendant Gorbec outlining, with specificity, the services rendered by Defendant Gorbec and the costs associated with those services. All money paid to Defendant Gorbec under this Order for the stability testing and technology transfer costs and services shall be subject to a final accounting review of the real costs to Defendant Gorbec as part of the ultimate resolution of all claims associated with the litigation between the parties in this case.

3. Defendant Gorbec Pharmaceutical Services, Inc. shall hereby be prohibited from transferring, using, or disclosing any information related to Plaintiff River's Edge Pharmaceuticals, LLC's ANDA or 510(k) products, including the Processes at issue, except as set out herein. Defendant Gorbec also shall hereby be prohibited from producing for itself or for any other person or entity, any of Plaintiff's ANDA or 510(k) products during the pendency of this litigation. However, Defendant Gorbec, without any apparent objection from Plaintiff, shall hereby be permitted to use the Processes for the development or production of products, other than Plaintiff's ANDA or 510(k) products, for itself or for any other person or entity. The Court specifically notes that neither this provision nor any other provision of this Order resolves the ultimate question of ownership as to the manufacturing processes involved in this case.

4. Because no provision of this Order resolves the question of ownership of the Processes at issue in this case, in order to protect the value of that interest, and to maintain the status quo in this case, Plaintiff River's Edge Pharmaceuticals, LLC and Defendant Gorbec Pharmaceutical Services, Inc. shall take steps to ensure confidentiality during the pendency of this litigation on the part of the manufacturer to which the technology transfer is made, any associated agents or affiliates of that manufacturer, and any persons or entities engaged by Defendant Gorbec as part of its work with other clients. Should it come to the attention of either Plaintiff or Defendant Gorbec that confidentiality has been or imminently

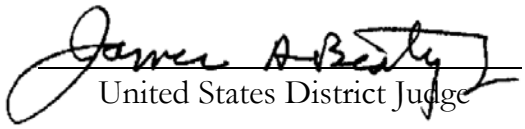
will be undermined in some way, the Court, upon notice from the parties, will afford either party the opportunity to seek redress to address that concern at that time.

IT IS FURTHER ORDERED that for the reasons stated herein, Plaintiff's request for expedited scheduling as to its claim for a declaratory judgment is hereby DENIED.

IT IS FURTHER ORDERED pursuant to Federal Rule of Civil Procedure 65(c) that this preliminary injunction is conditioned upon the posting by Plaintiff River's Edge Pharmaceuticals, LLC of a bond in the amount of $2,000,000. The Court finds, based upon the showings of the parties, that such a bond is appropriate and adequate to protect Defendant Gorbec Pharmaceutical Services, Inc., should it later be found that Defendant Gorbec Pharmaceutical Services, Inc. was wrongly enjoined or restrained. The Preliminary Injunction issued herein is effective on that date that Plaintiff River's Edge Pharmaceuticals, LLC posts the required $2,000,000 bond.

IT IS FINALLY ORDERED that this Court shall retain jurisdiction during the pendency of this litigation to interpret, enforce, or modify this Preliminary Injunction if appropriate.

This the 22nd day of March, 2011.



United States District Judge